

the method claims herein. Thus, the Examiner is using the method teachings of the applicants' own application to defeat the compound claims therein.

It is urged that a rejection of the claimed compounds for obviousness must be based on a comparison of their structure with the structure of compounds known in the art, not on an allegation of the obviousness of the method by which the compounds are prepared. Novel compounds are not rendered prima facie obvious by the fact that routine, standard, or predictable synthetic methods might have been involved in their preparation, for instance. Such considerations are extraneous to an investigation of a compound's patentability.

It is the applicants' belief that the compounds claimed in the present invention may have surprising and unexpected properties with respect to the various compounds shown in the prior art. However, any demonstration of such surprising and unexpected properties is impossible since the Examiner fails to specify which compounds of the prior art he deems closest in structure to the claimed compounds.

For instance, are the compounds of the present invention, which may be steroid carboxylate/carbonate, carbonate/carbonate, or sulfate/carbonate diesters, considered by the Examiner to be closest in structure to the ortho carbonates of the Stache et al. primary reference, or are they closest to the unhydrolyzed carbonate/carboxylate ortho esters of the Ercoli patent, or are they deemed by the Examiner to be closest in structure to the 17, 21-carboxylate esters which would be obtained by Ercoli et al. on esterification of the 21-hydroxy group of the 17-carboxylate monoester of a 17,21-dihydroxy compound obtained by hydrolysis of the Ercoli starting material?

The ambiguities and uncertainties inherent in the Examiner's present rejection, which fails to specify those compounds which the Examiner deems closest in structure to the

claimed compounds is accentuated by consideration of new Claims 26 and 27 respectively drawn to carbonate/carbonate diesters and sulfate/carbonate diesters. None of the patents cited by the Examiner show carbonate/carbonate diesters. Are these compounds deemed by the Examiner to be closest in structure to the ortho carbonates of the Stache et al. primary reference, for example? And what about the sulfonate/carbonate esters of Claim 27? Are such compounds deemed by the Examiner to be closest in structure to the cyclic ortho-carbonates of Stache et al., the cyclic ortho-carbonate /carboxylate ester starting compounds of Ercoli et al., or to the dicarboxylate esters which can be prepared using the methods taught in Ercoli from the monocarboxylate esters shown as intermediates?

The applicants are in a quandary as to what evidence to present of surprising and unexpected properties with respect to the closest prior art compounds, since the Examiner's rejection does not specify what those closest prior art compounds are. Rather, the rejection, as noted earlier, proceeds based on a method which is the subject of other claims in the present application and, thus, in roundabout fashion rejects the compound claims on the basis of a method first disclosed by the applicants in the same application. It is urged that such a rejection is unwarranted, since it is not based on the prior art but on the applicants' own teachings. The Examiner is respectfully urged to clarify and restate his rejection of the compound claims in a manner which rejects the compounds in an unambiguous fashion based on compounds deemed by the Examiner to be closest in structure.

The additional citation of the Sarett publication does not in any way clarify the rejection, nor does it seem to add to it. The publication merely shows 17-methyl and 17-ethyl carbonates of 17-hydroxy pregnadiene steroids.

The Examiner is further respectfully requested to reconsider and withdraw his rejection of method Claims 20-25 under 35 USC 103 as unpatentable over Ercoli et al. As has already been pointed out in the record, the ortho carbonate/carboxylate esters of Ercoli have a chiral carbon atom, as is evident from the formula shown in column 1, lines 55-60, for instance. In contrast, the compounds which are hydrolyzed according to the present invention (i.e. compounds like those shown in the Stache et al. reference of record), are ortho dicarbonate esters in which the carbon atom is symmetric, as is evident from the Stache et al. patent, column 1, lines 15-29. It is critical, in the hydrolysis of starting compounds having such a symmetric carbon atom, that a dilute aqueous acid must be employed. If a concentrated acid, such as is contemplated by Ercoli et al., is used, the hydrolysis product is not a 17-(monoalkyl carbonate)-21-hydroxy compound, which is then esterified according to the method of the present claims, but is instead a 17-hydroxy-21-ester compound.

The Ercoli reference fails in any way to recognize the criticality of the hydrolysis step and specifically teaches that "the acid reagent may be dilute or concentrated". Further, there is no teaching or suggestion in Ercoli of

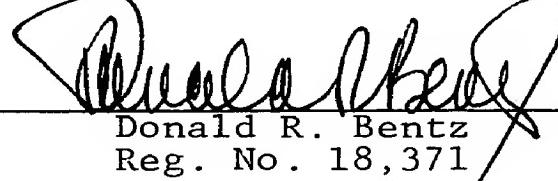
esterification of the intermediate 21-hydroxy compound with a halogenoformate, to give carbonate/carbonate diester products, nor is there any teaching or suggestion of esterification of the intermediate 21-hydroxy compound with a sulfonic acid halide (as in Claims 24 and 25) to form a sulfonate/carbonate diester.

In view of the amendments and arguments above, favorable reconsideration of the application with Claims 6-27 and passage of the application to issue with these claims are solicited.

Respectfully submitted,

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